Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy

Table 8. Antiretroviral Drug Use in Pregnant Women with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 1 of 18)

Note: When using FDCs, refer to other sections in Appendix B and Table 8 for information about the dosing and safety of individual drug components of the FDC during pregnancy.

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
NRTIs NRTIs are recommended for use as part of combination regimens, usually including 2 NRTIs with either an NNRTI or 1 or more PIs. Use of single or dual NRTIs alone is not recommended for treatment of HIV infection. See text for discussion of potential maternal and infant mitochondrial toxicity.				
Abacavir (ABC) *Ziagen* (ABC/3TC) *Epzicom* (ABC/DTG/3TC) *Triumeq* (ABC/3TC/ZDV) *Trizivir* **Note:** Generic products are available for some formulations.	**ABC (Ziagen)**[d] *Tablet:* • 300 mg *Oral Solution:* • 20 mg/mL **ABC/3TC (Epzicom):**[d] • ABC 600 mg/3TC 300 mg tablet **ABC/DTG/3TC (Triumeq):** • ABC 600 mg/DTG 50 mg/3TC 300 mg tablet **ABC/3TC/ZDV (Trizivir):**[d] • ABC 300 mg/3TC 150 mg/ZDV 300 mg tablet	**Standard Adult Doses** *ABC (Ziagen):* • ABC 300 mg twice daily or ABC 600 mg once daily, without regard to food *ABC/3TC (Epzicom):* • One tablet once daily without regard to food *ABC/DTG/3TC (Triumeq):* • One tablet daily without regard to food *ABC/3TC/ZDV (Trizivir):* • One tablet twice daily without regard to food **Pregnancy** *PKs in Pregnancy:* • PKs not significantly altered in pregnancy. *Dosing in Pregnancy:* • No change in dose indicated. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, ZDV, DTG).	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). HSRs occur in approximately 5% to 8% of nonpregnant individuals. A small percentage of reactions are fatal, and these fatal reactions are usually associated with re-challenge. Rate of reactions during pregnancy is unknown. Testing for HLA-B*5701 identifies patients at risk of reactions, and a patient's status **should be documented as negative** before initiating ABC. Patients should be educated regarding symptoms of HSR.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 2 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Emtricitabine (FTC) *Emtriva* (FTC/EFV/TDF) *Atripla* (FTC/BIC/TAF) *Biktarvy* (FTC/RPV/TDF) *Complera* (FTC/TAF) *Descovy* (FTC/EVG/c/TAF) *Genvoya* (FTC/RPV/TAF) *Odefsey* (FTC/EVG/c/TDF) *Stribild* (FTC/DRV/c/TAF) *Symtuza* (FTC/TDF) *Truvada* **Note:** Generic products are available for some formulations.	**FTC (Emtriva)** *Capsule:*[d] • 200 mg *Oral Solution:* • 10 mg/mL **FTC/EFV/TDF (Atripla):**[d] • FTC 200 mg/EFV 600 mg/TDF 300 mg tablet **FTC/BIC/TAF (Biktarvy):** • FTC 200 mg/BIC 50 mg/TAF 25 mg tablet **FTC/RPV/TDF (Complera):** • FTC 200 mg/RPV 25 mg/TDF 300 mg tablet **FTC/TAF (Descovy):** • FTC 200 mg/TAF 25 mg tablet **FTC/EVG/c/TAF (Genvoya):** • FTC 200 mg/EVG 150 mg/COBI 150 mg/TAF 10 mg tablet **FTC/RPV/TAF (Odefsey):** • FTC 200 mg/RPV 25 mg/TAF 25 mg tablet **FTC/EVG/c/TDF (Stribild):** • FTC 200 mg/EVG 150 mg/COBI 150 mg/TDF 300 mg tablet **FTC/DRV/c/TAF (Symtuza):** • FTC 200 mg/DRV 800 mg/COBI 150 mg/TAF 10 mg tablet **FTC/TDF (Truvada):**[d] • FTC 200 mg/TDF 300 mg tablet	**Standard Adult Doses** *FTC (Emtriva)* Capsule: • FTC 200 mg once daily without regard to food Oral Solution: • FTC 240 mg (24 mL) once daily without regard to food *FTC/EFV/TDF (Atripla):* • One tablet once daily at or before bedtime • Take on an empty stomach to reduce or mitigate side effects. *FTC/BIC/TAF (Biktarvy):* • One tablet once daily with or without food *FTC/RPV/TDF (Complera):* • One tablet once daily with food *FTC/TAF (Descovy):* • One tablet once daily with or without food *FTC/EVG/c/TAF (Genvoya):* • One tablet once daily with food *FTC/RPV/TAF (Odefsey):* • One tablet once daily with food *FTC/EVG/c/TDF (Stribild):* • One tablet once daily with food *FTC/DRV/c/TAF (Symtuza):* • One tablet once daily with food *FTC/TDF (Truvada):* • One tablet once daily without regard to food **Pregnancy** *PKs in Pregnancy:* • PKs of FTC are not significantly altered in pregnancy. *Dosing in Pregnancy:* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., TDF, TAF, EFV, RPV, DRV, EVG, BIC, COBI).	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). If patient has HBV/HIV coinfection, it is possible that a HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 3 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Lamivudine (3TC) *Epivir* (3TC/TDF) *Cimduo* (3TC/ZDV) *Combivir* (3TC/DOR/TDF) *Delstrigo* (3TC/DTG) *Dovato* (3TC/ABC) *Epzicom* (3TC/EFV/TDF) *Symfi* (3TC/EFV/TDF) *Symfi Lo* (3TC/TDF) *Temixys* (3TC/ABC/DTG) *Triumeq* (3TC/ABC/ZDV) *Trizivir* **Note:** Generic products are available for some formulations.	**3TC (Epivir)**[d] *Tablets:* • 150 mg • 300 mg *Oral Solution:* • 10 mg/mL **3TC/TDF (Cimduo):** • 3TC 300 mg/TDF 300 mg tablet **3TC/ZDV (Combivir):**[d] • 3TC 150 mg/ZDV 300 mg tablet **3TC/DOR/TDF (Delstrigo):** • 3TC 300 mg/DOR 100 mg/TDF 300 mg tablet **3TC/DTG (Dovato):** • 3TC 300 mg/DTG 50 mg tablet **3TC/ABC (Epzicom):**[d] • 3TC 300 mg/ABC 600 mg tablet **3TC/EFV/TDF (Symfi):** • 3TC 300 mg/EFV 600 mg/TDF 300 mg tablet **3TC/EFV/TDF (Symfi Lo):** • 3TC 300 mg/EFV 400 mg/TDF 300 mg tablet **3TC/TDF (Temixys):** • 3TC 300 mg/TDF 300 mg tablet **3TC/ABC/DTG (Triumeq):** • 3TC 300 mg/ABC 600 mg/DTG 50 mg tablet **3TC/ABC/ZDV (Trizivir):**[d] • 3TC 150 mg/ABC 300 mg/ZDV 300 mg tablet	**Standard Adult Doses** *3TC (Epivir):* • 3TC 150 mg twice daily or 300 mg once daily, without regard to food *3TC/TDF (Cimduo):* • One tablet once daily without regard to food *3TC/ZDV (Combivir):* • One tablet twice daily without regard to food *3TC/DOR/TDF (Delstrigo):* • One tablet once daily without regard to food *3TC/DTG (Dovato):* • One tablet once daily without regard to food *3TC/ABC (Epzicom):* • One tablet once daily without regard to food *3TC/EFV/TDF (Symfi or Symfi Lo):* • One tablet once daily on an empty stomach and preferably at bedtime *3TC/TDF (Temixys):* • One tablet once daily without regard to food *3TC/ABC/DTG (Triumeq):* • One tablet once daily without regard to food *3TC/ABC/ZDV (Trizivir):* • One tablet twice daily without regard to food **Pregnancy** *PKs in Pregnancy:* • PKs not significantly altered in pregnancy. *Dosing in Pregnancy:* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, DOR, DTG, EFV, TDF, ZDV)	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if the drug is stopped; see Hepatitis B Virus/HIV Coinfection. 3TC products that were developed specifically for treatment of HBV (e.g., Epivir-HBV) contain a lower dose of 3TC that **is not appropriate** for treatment of HIV.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 4 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Tenofovir Alafenamide (TAF) *Vemlidy* (TAF/BIC/FTC) *Biktarvy* (TAF/FTC) *Descovy* (TAF/EVG/c/FTC) *Genvoya* (TAF/FTC/RPV) *Odefsey* (TAF/DRV/c/FTC) *Symtuza*	**TAF (Vemlidy)** *Tablet:* • 25 mg **TAF/BIC/FTC (Biktarvy):** • TAF 25 mg/BIC 50 mg/FTC 200 mg tablet **TAF/FTC (Descovy):** • TAF 25 mg/FTC 200 mg tablet **TAF/EVG/c/FTC (Genvoya):** • TAF 10 mg/EVG 150 mg/COBI 150 mg/FTC 200 mg tablet **TAF/FTC/RPV (Odefsey):** • TAF 25 mg/FTC 200 mg/RPV 25 mg tablet **TAF/DRV/c/FTC (Symtuza):** • TAF 10 mg/DRV 800 mg/COBI 150 mg/FTC 200 mg tablet	**Standard Adult Doses** *TAF (Vemlidy):* • One tablet once daily with food *TAF/BIC/FTC (Biktarvy):* • One tablet once daily with or without food *TAF/FTC (Descovy):* • One tablet once daily with or without food • Same dose (TAF 25 mg) can be used with or without PK enhancers. *TAF/EVG/c/FTC (Genvoya):* • One tablet once daily with food *TAF/FTC/RPV (Odefsey):* • One tablet once daily with food *TAF/DRV/c/FTC (Symtuza):* • One tablet once daily with food **Pregnancy** *PKs in Pregnancy:* • Plasma PKs not significantly altered in pregnancy. *Dosing in Pregnancy:* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., BIC, COBI, DRV, EVG, FTC, RPV).	Low placental transfer to fetus.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats. Renal function should be monitored because of the potential for renal toxicity.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 5 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Tenofovir Disoproxil Fumarate (TDF) *Viread* (TDF/EFV/FTC) *Atripla* (TDF/3TC) *Cimduo* (TDF/FTC/RPV) *Complera* (TDF/DOR/3TC) *Delstrigo* (TDF/EVG/c/FTC *Stribild* (TDF/EFV/3TC) *Symfi* (TDF/EFV/3TC) *Symfi Lo* (TDF/3TC) *Temixys* (TDF/FTC) *Truvada* **Note:** Generic products are available for some formulations.	**TDF (Viread)** *Tablet:*[d] • 300 mg *Powder:* • 40 mg/1 g oral powder **TDF/EFV/FTC (Atripla):** • TDF 300 mg/EFV 600 mg/FTC 200 mg tablet **TDF/3TC (Cimduo):** • TDF 300 mg/3TC 300 mg tablet **TDF/FTC/RPV (Complera):** • TDF 300 mg/FTC 200 mg/RPV 25 mg tablet **TDF/DOR/3TC (Delstrigo):** • TDF 300 mg/DOR 100 mg/3TC 300 mg tablet **TDF/EVG/c/FTC (Stribild):** • TDF 300 mg/EVG 150 mg/COBI 150 mg/ FTC 200 mg tablet **TDF/EFV/3TC (Symfi):** • TDF 300 mg/EFV 600 mg/3TC 300 mg tablet **TDF/EFV/3TC (Symfi Lo):** • TDF 300 mg/EFV 400 mg/3TC 300 mg tablet **TDF/3TC (Temixys):** • TDF 300 mg/3TC 300 mg tablet **TDF/FTC (Truvada):** • TDF 300 mg/FTC 200 mg tablet	**Standard Adult Doses** *TDF (Viread)* Tablet: • TDF 300 mg once daily without regard to food Powder: • TDF 8 mg/kg daily (up to a maximum of TDF 300 mg). Take with food. *TDF/EFV/FTC (Atripla):* • One tablet once daily at or before bedtime. Take on an empty stomach to reduce side effects. *TDF/3TC (Cimduo):* • One tablet once daily without regard to food *TDF/FTC/RPV (Complera):* • One tablet once daily with food *TDF/DOR/3TC (Delstrigo):* • One tablet once daily without regard to food *TDF/EVG/c/FTC (Stribild):* • One tablet once daily with food *TDF/EFV/3TC (Symfi or Symfi Lo):* • One tablet once daily on an empty stomach and preferably at bedtime *TDF/3TC (Temixys):* • One tablet once daily without regard to food *TDF/FTC (Truvada):* • One tablet once daily without regard to food **Pregnancy** *PKs in Pregnancy:* • AUC is lower in third trimester than postpartum, but trough levels are adequate. *Dosing in Pregnancy:* • No change in dose is indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, COBI, DOR, EFV, EVG, FTC, RPV)	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). Studies in monkeys (at doses approximately 2-fold higher than those for human therapeutic use) show decreased fetal growth and reduction in fetal bone porosity within 2 months of starting maternal therapy. Human studies demonstrate no consistent link to low birth weight, but data are conflicting about potential effects on growth outcomes later in infancy. If patient has HBV/HIV coinfection, it is possible that an HBV flare may occur if TDF is stopped; see Hepatitis B Virus/HIV Coinfection. Renal function should be monitored because of potential for renal toxicity.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 6 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Zidovudine (ZDV) *Retrovir* (ZDV/3TC) *Combivir* (ZDV/ABC/3TC) *Trizivir* **Note:** Generic products are available for all formulations.	**ZDV (Retrovir)** *Capsule:* • 100 mg *Tablet:* • 300 mg *Oral Solution:* • 10 mg/mL *IV Solution:* • 10 mg/mL **ZDV/3TC (Combivir):** • ZDV 300 mg/3TC 150 mg tablet **ZDV/ABC/3TC (Trizivir):** • ZDV 300 mg/ABC 300 mg/3TC 150 mg tablet	**Standard Adult Doses** *ZDV (Retrovir):* • ZDV 300 mg twice daily or ZDV 200 mg three times a day without regard to food • Patients in active labor should receive ZDV 2 mg/kg IV as a loading dose, followed by ZDV 1 mg/kg/hour continuous infusion from beginning of active labor until delivery. *ZDV/3TC (Combivir):* • One tablet twice daily without regard to food *ZDV/ABC/3TC (Trizivir):* • One tablet twice daily without regard to food **Pregnancy** *PKs in Pregnancy:* • PKs not significantly altered in pregnancy. *Dosing in Pregnancy:* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, 3TC)	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects).	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 7 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
NNRTI NNRTIs are recommended for use in combination regimens with 2 NRTI drugs. Hypersensitivity reactions, including hepatic toxicity and rash, more common in women; unclear if increased in pregnancy.				
Doravirine (DOR) *Pifeltro* (DOR/3TC/TDF) *Delstrigo*	**DOR (Pifeltro):** • 100 mg tablet **DOR/3TC/TDF (Delstrigo):** • DOR 100 mg/ 3TC 300 mg/ TDF 300 mg tablet	**Standard Adult Doses** *DOR (Pifeltro):* • DOR 100 mg once daily with or without food *DOR/3TC/TDF (Delstrigo):* • One tablet once daily with or without food **Pregnancy** *PKs in Pregnancy:* • No PK studies in human pregnancy. *Dosing in Pregnancy:* • Insufficient data to make dosing recommendations. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, TDF)	No data are available on the placental transfer of DOR in humans, but animal studies suggest that DOR crosses the placenta. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	December 24, 2019
Efavirenz (EFV) *Sustiva* (EFV/FTC/TDF) *Atripla* (EFV/3TC/TDF) *Symfi* (EFV/3TC/TDF) *Symfi Lo* **Note:** Generic products are available for some formulations.	**EFV (Sustiva)**[d] *Capsules:* • 50 mg • 200 mg *Tablet:* • 600 mg **EFV/FTC/TDF (Atripla):** • EFV 600 mg/FTC 200 mg/TDF 300 mg tablet **EFV/3TC/TDF (Symfi):** • EFV 600 mg/3TC 300 mg/TDF 300 mg tablet **EFV/3TC/TDF (Symfi Lo):** • EFV 400 mg/3TC 300 mg/TDF 300 mg tablet	**Standard Adult Doses** *EFV (Sustiva):* • EFV 600 mg once daily at or before bedtime • Take on an empty stomach to reduce side effects. *EFV/FTC/TDF (Atripla):* • One tablet once daily at or before bedtime • Take on an empty stomach to reduce side effects. *EFV/3TC/TDF (Symfi or Symfi Lo):* • One tablet once daily on an empty stomach and preferably at bedtime **Pregnancy** *PKs in Pregnancy:* • AUC is decreased during the third trimester compared with postpartum, but nearly all third-trimester participants exceeded target exposure.	Moderate placental transfer to fetus.[b] The FDA advises women to avoid becoming pregnant while taking EFV and advises health care providers to avoid administration during the first trimester of pregnancy, as fetal harm may occur. However, the data on more than 7,900 periconception EFV exposures from Botswana rules out a ≥3-fold increased risk of NTDs. As a result, the current Perinatal Guidelines do not restrict the use of EFV in pregnant women or in women who are planning to become pregnant. This is consistent with both the British HIV Association and WHO guidelines for use of ARV drugs in pregnancy. EFV should be continued in pregnant women who are on a virally suppressive, EFV-based regimen, because ARV drug changes during pregnancy may be associated with loss of viral control and an increased risk of perinatal transmission (see Pregnant Women Living with HIV Who are Currently Receiving Antiretroviral Therapy).	January 17, 2020

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 8 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Efavirenz, continued		*Dosing in Pregnancy:* • No change in dose is indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., 3TC, FTC, TDF)		
Etravirine (ETR) *Intelence*	**Tablets:** • 25 mg • 100 mg • 200 mg For patients who are unable to swallow tablets whole, the tablets may be dispersed in a glass of water.	**Standard Adult Dose:** • ETR 200 mg twice daily with food **Pregnancy** *PKs in Pregnancy:* • PK data in pregnancy suggest 1.2-fold to 1.6-fold increases in ETR exposure during pregnancy. *Dosing in Pregnancy:* • No change in dose indicated.	Placental transfer varies; it is usually in the moderate to high categories, ranging from 0.19–4.25.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	December 24, 2019
Nevirapine (NVP) *Viramune* *Viramune XR* **Note:** Generic products are available for some formulations.	**NVP (Viramune)** *Tablet:* • 200 mg[d] *Oral Suspension:* • 50 mg/5 mL[d] **Viramune XR** *Tablets:* • 100 mg • 400 mg[d]	**Standard Adult Doses:** • NVP 200 mg once daily (using Viramune immediate release) for a 14-day lead-in period; thereafter, NVP 200 mg twice daily or 400 mg (using Viramune XR tablet) once daily, without regard to food. • Repeat lead-in period if therapy is discontinued for >7 days. • In patients who develop mild-to-moderate rash without constitutional symptoms during the lead-in period, continue lead-in dosing until rash resolves, but administer for ≤28 days total. **Pregnancy** *PKs in Pregnancy:* • PKs of immediate-release tablets not significantly altered in pregnancy. • No data available on extended-release formulations in pregnancy. *Dosing in Pregnancy:* • No change in dose indicated.	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects and 2-fold increase in cardiovascular and genitourinary defects). There is an increased risk of symptomatic liver toxicity when first initiating therapy in women with CD4 counts ≥250/mm^3. Liver toxicity is often associated with a rash and can be fatal. Pregnancy does not appear to increase this risk. NVP should be initiated in pregnant women with CD4 counts ≥250 cells/mm^3 only if benefit clearly outweighs risk. There is a potential increased risk of life-threatening hepatotoxicity in women with high CD4 counts. Elevated transaminase levels at baseline may increase the risk of NVP toxicity. Women who become pregnant while taking NVP-containing regimens and who are tolerating their regimens well can continue taking those regimens, regardless of their CD4 counts.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 9 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Rilpivirine (RPV) *Edurant* (RPV/FTC/TDF) *Complera* (RPV/DTG) *Juluca* (RPV/FTC/TAF) *Odefsey*	**RPV (Edurant)** *Tablets:* • 25 mg **RPV/FTC/TDF (Complera):** • RPV 25 mg/FTC 200 mg/TDF 300 mg tablet **RPV/DTG (Juluca):** • RPV 25 mg/DTG 50 mg tablet **RPV/FTC/TAF (Odefsey):** • RPV 25 mg/FTC 200 mg/TAF 25 mg tablet	**Standard Adult Doses** *RPV (Edurant):* • RPV 25 mg once daily with food *RPV/FTC/TDF (Complera):* • One tablet once daily with food *RPV/DTG (Juluca):* • One tablet once daily with food *RPV/FTC/TAF (Odefsey):* • One tablet once daily with food **Pregnancy** *PKs in Pregnancy:* • RPV PKs are highly variable during pregnancy. RPV AUC and trough concentration are 20% to 50% lower in pregnancy than postpartum. While most pregnant women exceeded target exposure, those with detectable viral loads had lower RPV troughs. *Dosing in Pregnancy:* • While RPV plasma concentration is reduced during pregnancy, higher-than-standard doses have not been studied, and there is not enough data available to recommend a dosing change during pregnancy. Pregnant women receiving standard dosing should have their viral loads monitored more frequently than women who are not receiving RPV. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., DTG, FTC, TAF, TDF).	Moderate to high placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects). Two-drug regimens (e.g., the RPV/DTG FDC) **are not recommended** for use in pregnancy.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 10 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
PIs PIs block the activity of the protease enzyme, which is required to assemble new HIV viral particles that are capable of infecting new cells.				
Atazanavir (ATV) *Reyataz* **Note:** Generic products are available for some formulations. **Note:** ATV must be combined with low-dose RTV boosting in pregnancy. (ATV/c) *Evotaz*	**ATV (Reyataz)** *Capsules:* • 100 mg (generic product only) • 150 mg[d] • 200 mg[d] • 300 mg[d] *Oral Powder:* • 50 mg packet **ATV/c (Evotaz):** • ATV 300 mg/ COBI 150 mg tablet	**Standard Adult Doses** *In ARV-Naive Patients without RTV Boosting:* • ATV 400 mg once daily with food; ATV without RTV boosting **is not recommended** when used with TDF, H2-receptor antagonists, PPIs, or during pregnancy. *In ARV-Naive Patients with RTV Boosting:* • ATV 300 mg plus RTV 100 mg once daily with food • When combined with EFV in ARV-naive patients: ATV 400 mg plus RTV 100 mg once daily with food *In ARV-Experienced Patients:* • ATV 300 mg plus RTV 100 mg once daily with food • **Do not use** with PPIs or EFV *In ARV-Experienced Patients Who Are Receiving an H2-Receptor Antagonist:* • ATV 300 mg plus RTV 100 mg once daily with food *In ARV-Experienced Patients Who Are Receiving an H2-Receptor Antagonist and TDF:* • ATV 400 mg plus RTV 100 mg once daily with food *Powder Formulation:* • Oral powder is taken with RTV once daily with food at the same recommended adult dose as the capsules. *ATV/c (Evotaz):* • One tablet once daily with food **Pregnancy** *PKs in Pregnancy* ATV (Reyataz): • ATV concentrations are reduced during pregnancy, and they are further reduced when ATV is given concomitantly with TDF or an H2-receptor antagonist. ATV/c (Evotaz): • Use of ATV/c **is not recommended** during pregnancy, because ATV trough concentrations are 80% to 85% lower than the ATV concentrations seen in nonpregnant adults.	Low placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). Must be given with RTV boosting in pregnancy. Effect of *in utero* ATV exposure on infant indirect bilirubin levels is unclear. Nonpathologic elevations of neonatal bilirub have been observed in some, but not all, clinical trials to date. Oral powder (but **not** capsules) contains phenylalanine, which can be harmful to patients with phenylketonuria. Use of ATV/c **is not recommended** during pregnancy. See Recommendations for Use of Antiretroviral Drugs During Pregnancy, Table 4, and Table 5 for discussions about avoiding the use of ATV/c during pregnancy.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 11 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Atazanavir, continued		*Dosing in Pregnancy* ATV (Reyataz): • Use of unboosted ATV **is not recommended** during pregnancy. • Use of ATV **is not recommended** for ARV-experienced pregnant women who are taking TDF and an H2-receptor antagonist. • Use of an increased dose (ATV 400 mg plus RTV 100 mg once daily with food) during the second and third trimesters results in plasma ATV concentrations equivalent to those seen in nonpregnant adults receiving standard dosing. Although some experts recommend increased ATV dosing in all women during the second and third trimesters, the package insert recommends increased ATV dosing only for ARV-experienced pregnant women in the second and third trimesters who are also receiving either TDF or an H2-receptor antagonist. ATV/c (Evotaz): • Insufficient data to make dosing recommendation in pregnancy (see COBI). For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI).		
Darunavir (DRV) *Prezista* **Note:** Must be combined with low-dose RTV or COBI boosting. (DRV/c) *Prezcobix* (DRV/c/FTC/TAF) *Symtuza*	**DRV (Prezista)** *Tablet:* • 75 mg • 150 mg • 600 mg • 800 mg *Oral Suspension:* • 100 mg/mL **DRV/c (Prezcobix):** • DRV/c 800 mg/150 mg tablet **DRV/c/FTC/TAF (Symtuza):** • DRV 800 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg tablet	**Standard Adult Doses** *ARV-Naive Patients:* • DRV 800 mg plus RTV 100 mg once daily with food • DRV 800 mg plus COBI 150 mg once daily with food *ARV-Experienced Patients* If Patient Has No DRV Resistance Mutations: • DRV 800 mg plus RTV 100 mg once daily with food • DRV 800 mg plus COBI 150 mg once daily with food If Any DRV Resistance Mutations Are Present: • DRV 600 mg plus RTV 100 mg twice daily with food *DRV/c (Prezcobix):* • One tablet once daily with food *DRV/c/FTC/TAF (Symtuza):* • One tablet once daily with food **Pregnancy** *PKs in Pregnancy:* • Decreased exposure in pregnancy with use of DRV/r.	Low placental transfer to fetus.[b] No evidence of teratogenicity in mice, rats, or rabbits. No evidence of human teratogenicity. Must be boosted with low-dose RTV. The Panel **does not recommend** once-daily dosing with DRV/r during pregnancy or the use of DRV/c during pregnancy. If a DRV/c regimen is continued during pregnancy, viral load should be monitored frequently.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 12 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Darunavir, continued		*Dosing in Pregnancy:* • The Panel **does not recommend** once-daily dosing with DRV/r during pregnancy or the use of DRV/c during pregnancy. • Twice-daily DRV/r dosing (DRV 600 mg plus RTV 100 mg with food) is recommended for all pregnant women. • Increased twice-daily DRV dose (DRV 800 mg plus RTV 100 mg with food) during pregnancy does not result in an increase in DRV exposure and **is not recommended**. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI, FTC, TAF)		
Lopinavir/ Ritonavir (LPV/r) *Kaletra*	**LPV/r (Kaletra)** *Tablets:* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution:* • Each 5 mL contains LPV/r 400 mg/100 mg	**Standard Adult Doses:** • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/200 mg once daily *Tablets:* • Take without regard to food. *Oral Solution:* • Take with food. *With EFV or NVP in PI-Naive or PI-Experienced Patients:* • LPV/r 500 mg/125 mg tablets twice daily without regard to meals (use a combination of two LPV/r 200 mg/50 mg tablets and one LPV/r 100 mg/25 mg tablet), *or* • LPV/r 520 mg/130 mg oral solution (6.5 mL) twice daily with food **Pregnancy** *PKs in Pregnancy:* • With twice-daily dosing, LPV exposure is reduced in pregnant women who receive standard adult doses; increasing the dose by 50% results in exposure equivalent to that seen in nonpregnant adults receiving standard doses. • No PK data are available for once-daily dosing in pregnancy. *Dosing in Pregnancy:* • Once-daily dosing **is not recommended** during pregnancy. • Some experts recommend that an increased dose (i.e., LPV/r 600 mg/150 mg twice daily without regard to meals or LPV/r 500 mg/125 mg twice daily without regard to meals) should be used in the second and third trimesters, especially in PI-experienced pregnant women and women who start treatment during pregnancy with a baseline viral load >50 copies/mL. • When standard dosing is used, monitor virologic response and, if possible, LPV drug levels.	Low placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). Oral solution contains 42% alcohol and 15% propylene glycol and **is not recommended** for use in pregnancy. Once-daily LPV/r dosing **is not recommended** during pregnancy.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 13 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Entry Inhibitors Entry and attachment inhibitors block viral binding or fusion of HIV to host cells.				
Ibalizumab (IBA) *Trogarzo*	**IBA (Trogarzo):** • Solution for IV infusion is available in single-dose vials	**Standard Adult Dose:** • IBA 2,000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks **Pregnancy** *PKs in Pregnancy:* • No PK studies in human pregnancy. *Dosing in Pregnancy:* • Insufficient data to make dosing recommendations.	No data available, but placental transfer of IBA, a monoclonal antibody, is possible. Insufficient data to assess for teratogenicity in humans.	December 24, 2019
Maraviroc (MVC) *Selzentry*	**MVC (Selzentry)** *Tablets:* • 150 mg • 300 mg	**Standard Adult Doses:** • MVC 300 mg twice daily with or without food • MVC should only be used for patients with CCR5-tropic virus (and no X4-tropic virus). *Dose Adjustments:* • Increase to MVC 600 mg twice daily when used with the potent CYP3A inducers EFV, ETR, and rifampin. • Decrease to MVC 150 mg twice daily when used with CYP3A inhibitors, which includes all PIs except TPV/r and itraconazole. **Pregnancy** *PKs in Pregnancy:* • A PK study in human pregnancy demonstrated a 20% to 30% overall decrease in MVC AUC, but C_{trough} exceeded the recommended minimum concentration of 50 ng/mL. *Dosing in Pregnancy:* • Adjusting the standard adult MVC dose for concomitant use with ARV drugs seems appropriate.	Moderate placental transfer to fetus.[b] No evidence of teratogenicity in rats or rabbits; insufficient data to assess for teratogenicity in humans.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 14 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
INSTIs INSTIs block integrase, the viral enzyme that catalyzes the two-step process that inserts HIV DNA into the genome of the host cell.				
Bictegravir/ Emtricitabine/ Tenofovir Alafenamide (BIC/FTC/TAF) *Biktarvy* **Note:** BIC is only available as part of an FDC tablet.	**BIC/FTC/TAF (Biktarvy):** • BIC 50 mg/FTC 200 mg/TAF 25 mg tablet	**Standard Adult Dose:** • One tablet once daily with or without food **Pregnancy** *PKs in Pregnancy:* • No PK studies in human pregnancy. *Dosing in Pregnancy:* • Insufficient data to make dosing recommendations. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF).	No data are available on placental transfer of BIC. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. BIC can be taken with food at the same time as any preparation containing iron or calcium, including prenatal vitamins, but should not be administered within 2 hours of these preparations when taken on an empty stomach. BIC can be taken at least 2 hours before or 6 hours after antacids containing aluminum or magnesium.	December 24, 2019
Dolutegravir (DTG) *Tivicay* (DTG/3TC) *Dovato* (DTG/RPV) *Juluca* (DTG/ABC/3TC) *Triumeq*	**DTG (Tivicay):** • DTG 50 mg tablet **DTG/3TC (Dovato):** • DTG 50 mg/3TC 300 mg tablet **DTG/RPV (Juluca):** • DTG 50 mg/ RPV 25 mg tablet **DTG/ABC/3TC (Triumeq):** • DTG 50 mg/ ABC 600 mg/3TC 300 mg tablet	**Standard Adult Doses** *In ARV-Naive or ARV-Experienced (but INSTI-Naive) Patients* DTG (Tivicay): • One tablet once daily, without regard to food DTG/3TC (Dovato): • One tablet once daily, without regard to food DTG/RPV (Juluca): • One tablet once daily with food DTG/ABC/3TC (Triumeq): • One tablet once daily, without regard to food *In ARV-Naive or ARV-Experienced (but INSTI-Naive) Patients Who Are Also Receiving EFV, FPV/r, TPV/r, or Rifampin* DTG (Tivicay): • One tablet twice daily, without regard to food *In INSTI-Experienced Patients* DTG (Tivicay): • One tablet twice daily, without regard to food **Pregnancy** *PKs in Pregnancy:* • AUC may be decreased during the third trimester compared with postpartum, but exposures during pregnancy are well above those needed to inhibit viral replication.	High placental transfer to fetus.[b] No evidence of teratogenicity in rats or rabbits. In pregnancy surveillance data from Botswana, there was a slightly increased risk of NTDs in infants born to women who initiated DTG prior to pregnancy and who were receiving it at the time of conception. DTG may be used as part of a *Preferred* regimen in all pregnant women at all gestational ages and as part of an *Alternative* regimen in women who are trying to conceive. Clinicians should discuss the risks and benefits of DTG use with the patient. For more information, see Updated Guidance About the Use of Dolutegravir in Pregnancy in Recommendations for Use of Antiretroviral Drugs During Pregnancy. To maximize DTG absorption, doses should not be administered within 2 hours of ingesting any preparation that contains minerals such as iron or calcium, including prenatal vitamins.	December 12, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 15 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Dolutegravir, continued		*Dosing in Pregnancy:* • No change in dose indicated. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., ABC, 3TC, RPV).		
Elvitegravir (EVG) **Note:** As of October 2017, the single-drug formulation of EVG (Vitekta) is no longer available. (EVG/c/FTC/TAF) *Genvoya* (EVG/c/FTC/TDF) *Stribild*	**EVG/c/FTC/TAF (Genvoya):** • EVG 150 mg/ COBI 150 mg/ FTC 200 mg/ TAF 10 mg tablet **EVG/c/FTC/TDF (Stribild):** • EVG 150 mg/ COBI 150 mg/ FTC 200 mg/ TDF 300 mg tablet	**Standard Adult Dose** *Genvoya and Stribild:* • One tablet once daily with food **Pregnancy** *PKs in Pregnancy:* • PK studies in women who received EVG/c demonstrated significant reduction in EVG plasma exposure during pregnancy. *Dosing in Pregnancy:* • EVG plasma concentrations are reduced with use of standard adult doses during pregnancy; however, higher-than-standard doses of EVG have not been studied. Insufficient data are available to recommend a dose for use in pregnancy. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., COBI, FTC, TAF).	Evidence of high placental transfer of EVG and low transfer of COBI.[b] Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. EVG/c **is not recommended** for use in pregnancy. For women who become pregnant while taking EVG/c, consider switching to a more effective, recommended regimen. If a woman continues taking a regimen that contains EVG/c, doses should be administered with a meal and should not be administered within 2 hours of ingesting any preparation that contains minerals such as iron or calcium, including prenatal vitamins.	December 24, 2019
Raltegravir (RAL) *Isentress* *Isentress HD*	**RAL (Isentress)** *Film-Coated Tablets:* • 400 mg *Chewable Tablets:* • 25 mg • 100 mg **RAL (Isentress HD)** *Film-Coated Tablets:* • 600 mg	**Standard Adult Doses** *In Patients Who Are Not Receiving Rifampin:* • RAL 400-mg, film-coated tablets twice daily without regard to food • Two RAL 600-mg, film-coated tablets (1,200 mg) once daily without regard to food for ARV-naive patients or patients who are already virologically suppressed on an initial regimen of RAL 400 mg twice daily • Chewable tablets and oral suspension doses **are not interchangeable** with either film-coated tablets or each other. *In Patients Who Are Receiving Rifampin:* • Two RAL 400-mg, film-coated tablets (800 mg) twice daily without regard to food **Pregnancy** *PKs in Pregnancy:* • Decreased drug concentrations in third trimester are not of sufficient magnitude to warrant a change in dosing.	High placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). There is a case report of markedly elevated liver transaminases with RAL use in late pregnancy. Severe, potentially life-threatening, and fatal skin and HSRs have been reported in nonpregnant adults. RAL chewable tablets contain phenylalanine. To maximize RAL absorption, doses should not be administered within 2 hours of ingestion of any preparation containing minerals such as iron or calcium, including prenatal vitamins.	January 17, 2020

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 16 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Integrase Inhibitors, continued				
Raltegravir, continued		*Dosing in Pregnancy:* • No change in dose is indicated. • Once-daily dosing (i.e., two RAL 600-mg, film-coated tablets) **should not be used** in pregnant women until more information is available.		
Pharmacoenhancers Pharmacoenhancers reduce the metabolism of antiretroviral drugs and prolong their presence in plasma, allowing for more convenient dosing regimens.				
Cobicistat (COBI) *Tybost* (ATV/c) *Evotaz* (EVG/c/FTC/TAF) *Genvoya* (DRV/c) *Prezcobix* (EVG/c/FTC/TDF) *Stribild* (DRV/c/FTC/TAF) *Symtuza*	**COBI (Tybost)** *Tablet:* • COBI 150 mg **ATV/c (Evotaz):** • ATV 300 mg/COBI 50 mg tablet **EVG/c/FTC/TAF (Genvoya):** • EVG 150 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg tablet **DRV/c (Prezcobix):** • DRV 800 mg/COBI 150 mg tablet **EVG/c/FTC/TDF (Stribild):** • EVG 150 mg/COBI 150 mg/FTC 200 mg/TDF 300 mg tablet **DRV/c/FTC/TAF (Symtuza):** • DRV 800 mg/COBI 150 mg/FTC 200 mg/TAF 10 mg tablet	**Standard Adult Doses** *COBI (Tybost):* • When used as an alternative PK booster with ATV or DRV, the dose is one tablet once daily with food *ATV/c (Evotaz):* • One tablet once daily with food *EVG/c/FTC/TAF (Genvoya):* • One tablet once daily with food *DRV/c (Prezcobix):* • One tablet once daily with food *EVG/c/FTC/TDF (Stribild):* • One tablet once daily with food *DRV/c/FTC/TAF (Symtuza):* • One tablet once daily with food **Pregnancy** *PKs in Pregnancy:* • Based on limited data, COBI exposure and its pharmaco-enhancing effect on ATV, DRV, and EVG are markedly reduced in pregnancy. • When coadministered with COBI, TAF exposure is not significantly different between pregnancy and the postpartum period. *Dosing in Pregnancy:* • While COBI exposure is markedly reduced during pregnancy, higher-than-standard doses have not been studied. The Panel recommends RTV as the preferred pharmaco-enhancer for PIs and INSTIs during pregnancy until more data are available on COBI activity during pregnancy. For guidance about the use of combination products in pregnancy, please see the specific sections on other components (i.e., FTC, TAF, TDF, ATV, DRV, EVG).	Low placental transfer to fetus.[b] No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects). Use of COBI-boosted ATV, DRV, or EVG **is not recommended** in pregnancy.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 17 of 18)

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Ritonavir (RTV) *Norvir* (LPV/r) *Kaletra*	**RTV (Norvir)** *Capsules:* • RTV 100 mg *Tablets:* • RTV 100 mg *Oral Solution:* • RTV 80 mg/mL *Powder:* • RTV 100 mg/sachet **LPV/r (Kaletra)** *Tablets:* • LPV/r 200 mg/50 mg • LPV/r 100 mg/25 mg *Oral Solution:* • Each 5 mL contains LPV/r 400 mg/100 mg	**Standard Adult Dose of RTV (Norvir) When Used as PK Booster for Other PIs:** • RTV 100–400 mg per day in one or two divided doses (refer to other PI sections for specific dosing recommendations) *Tablet:* • Take with food *Capsule or Oral Solution:* • To improve tolerability, take with food if possible **Standard Adult Doses of LPV/r (Kaletra):** • LPV/r 400 mg/100 mg twice daily, *or* • LPV/r 800 mg/200 mg once daily *Tablets:* • Take without regard to food. *Oral Solution:* • Take with food. *With EFV or NVP in PI-Naive or PI-Experienced Patients:* • LPV/r 500 mg/125 mg tablets twice daily without regard to meals (use a combination of two LPV/r 200 mg/50 mg tablets and one LPV/r 100 mg/25 mg tablet), *or* • LPV/r 520 mg/130 mg oral solution (6.5 mL) twice daily with food **Pregnancy** *PKs in Pregnancy:* • Lower RTV levels are seen during pregnancy than during postpartum, which may reduce the pharmaco-enhancing effect of RTV in pregnancy. *RTV Dosing in Pregnancy:* • No dose adjustment necessary when RTV is used as booster. *LPV/r Dosing in Pregnancy:* • Once-daily dosing **is not recommended** during pregnancy. • Some experts recommend that an increased dose (i.e., LPV/r 600 mg/150 mg twice daily without regard to meals or LPV/r 500 mg/125 mg twice daily without regard to meals) should be used in the second and third trimesters, especially in PI-experienced pregnant women and women who start treatment during pregnancy with a baseline viral load >50 copies/mL. • When standard dosing is used, monitor virologic response and, if possible, LPV drug levels. For guidance about use of combination products in pregnancy, please see the specific sections on other components (i.e., LPV/r).	Low placental transfer to fetus.[b] No evidence of increased risk of human teratogenicity (can rule out 1.5-fold increase in overall birth defects). RTV should only be used as low-dose booster for other PIs. RTV oral solution contains 43% alcohol and therefore **is not recommended** for use during pregnancy, because there is no known safe level of alcohol exposure during pregnancy. LPV/r oral solution contains 42% alcohol and 15% propylene glycol and **is not recommended** for use in pregnancy. Once-daily LPV/r dosing **is not recommended** during pregnancy.	December 24, 2019

Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy[a] (page 18 of 18)

[a] Individual ARV drug dosages may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the Adult and Adolescent Guidelines, Appendix B, Table 10).

[b] Placental transfer categories are determined by mean or median cord blood/maternal delivery plasma drug ratio:

High: >0.6 **Moderate:** 0.3–0.6 **Low:** <0.3

[c] Only indicated for use in chronic HBV virus infection in adults.

[d] Generic product available

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; AUC = area under the curve; BIC = bictegravir; CD4 = CD4 T lymphocyte; COBI = cobicistat; CYP = cytochrome P; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FDA = Food and Drug Administration; FDC = fixed-dose combination; FTC = emtricitabine; HBV = hepatitis b virus; HSR = hypersensitivity reaction; IBA =ibalizumab; INSTI = integrase strand transfer inhibitor; IV = intravenous; LPV = lopinavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NTD = neural tube defect; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; PPI = proton pump inhibitor; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; TPV/r = tipranavir/ritonavir; WHO = World Health Organization; ZDV = zidovudine